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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/722,306

11/24/2003

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9308

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03/14/2008

EXAMINER

HOLMES, REX R

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

03/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,306	EDMAN ET AL.	
	Examiner	Art Unit	
	REX HOLMES	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21, 23-27 and 37-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21, 23-27, 37-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/13/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 21, 23-27, 37-43, and 45-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Kroll et al. (U.S. Pat. 7,203,550 hereinafter “Kroll”).

3. Regarding claims 21, 25-27, 37-43, and 45-47, Kroll discloses an implantable device with a current for fighting infection, wherein a current of 10-100mA/cm² is provided to allow antibiotics to penetrate a biofilm and destroy bacteria (Col. 1, ll. 54-58). Kroll discloses a fully implantable system inserted through the vasculature, with one electrode located in right atrium and one located in the right ventricle (Col. 2, ll. 5-11). Kroll further discloses that the device works in conjunction with antibiotics (Col. 11, ll. 47-49). The device of Kroll has a surface adapted to contact tissue, the surface having a surface charge of between 10-100 mA/cm² and the surface charge being time dependent, thus it achieves the same device limitations and further is capable of achieving the same inherent results and respective benefits as the claimed device.

4. Regarding claims 23-24, Kroll discloses the claimed invention as described in detail above, but Kroll fails to disclose that cells are migrated and that those cells are

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endothelial or fibroblast cells. Kroll discloses the current density that is the same as the current density disclosed in the application, so it be inherent that the Kroll invention would cause cell migration since the values are similar and would cause migration of both endothelial and fibroblast cells.

5. Regarding claims 40 and 41, since the specification is silent as to how the device communicates with the electrodes if they are not affixed to the device the examiner is taking the position that the electrodes are connected remotely to the device. In this case the electrodes of Kroll are remotely connected to the device and thus anticipate claims 40 and 41.

6. Regarding claim 42, the device of Kroll is capable of being attached outside of the body and have the leads implanted.

7. Regarding claim 46, the electrodes of Kroll are capable of being removed from the body and have biofluids sampled from them.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll.

11. Regarding claim 44, Kroll discloses the claimed invention except for the electrode being separated from tissue by a semipermeable layer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable device with a current for infection control in combination with an injected antibiotic as taught by Kroll, with electrodes coated in antibiotics since it was known in the art that lead electrodes covered in a semipermeable layer of an antibiotic, provides the predictable result of direct placement of an antibiotic near implantation sites to fight infection as opposed to injected antibiotics that take time to get to the implantation site.

Response to Arguments

12. Applicant's arguments filed 11/13/07 regarding 35 USC 102(e) and 35 USC 103(a) have been fully considered but they are not persuasive.

13. The Applicant argues that Kroll does not guide selected cell types to produce a longer useful lifetime of the device by limiting undesirable cellular responses to foreign bodies. The Examiner respectfully disagrees. The device of Kroll has a surface adapted to contact tissue, the surface having a surface charge of between 0.01-100 mA/cm² and the surface charge being time dependent, thus it achieves the same device limitations and further achieves the same inherent results and respective benefits as the

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claimed device. It is further noted that the desired results of migrating cell types to produce a longer useful lifetime are not germane to the patentability of these device claims.

14. The Applicant further requests that the Examiner provide evidence that it is known in the art to surround a device with a antibiotic to provide direct placement of an antibiotic near the implantation site. The Kroll reference specifically discloses that a biocide can be supplied at the site of implantation surrounding the cardiac stimulation device (Col. 11, ll. 57-62). Further evidence of obviousness can be found in any one of the patents classified in 604/265 or in one of the following patents. Woloszko et al. (U.S. Pat. 5,755,758) – Antibacterial coated lead. Fox, Jr. et al. (U.S. Pat. 5,019,096) – Infection-resistant compositions for medical device and surfaces. De Leon et al. (4,952,419) – Antimicrobial coated implants. Ragheb et al. (U.S. Pat. 6,299,604) – Coated implantable medical device.

15. Applicant's arguments, see Applicant's Remarks, filed 11/13/07, with respect to the rejections under 35 USC 112 have been fully considered and are persuasive. The rejection of claims 21-27 and 37-47, under 35 USC 112 have been withdrawn.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REX HOLMES whose telephone number is (571)272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. H./

Examiner, Art Unit 3762

/George R Evanisko/

Primary Examiner, Art Unit 3762